510(k) Summary

K113197 FEB - 2 2012

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

510(k) Submitter..... 3M Unitek Corporation, 2724 South Peck Road, Monrovia, CA 91016-5097

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Date Summary was Prepared..... October 28, 2011

Trade /Device Name..... *APC™ Flash-Free Adhesive*

Common Name..... *Adhesive, Bracket and Tooth Conditioner, Resin*

Classification Name..... *Bracket adhesive resin and tooth conditioner (21 CFR 872.3750, Class II, Product Code: DYH, Subsequent Product Code: NJM and EJF)*

Predicate Devices:
Company: 3M Unitek Corporation
Device: Adhesive Precoated Brackets (K911271)

Company: 3M Unitek Corporation
Device: APC™ Plus Adhesive (K020394)

Device Description:
APC™ Flash-Free Adhesive is a light cure orthodontic adhesive intended for use in bonding appliances for orthodontic treatment. It consists of a resin-saturated mat that is attached to the bonding base of metal brackets, ceramic brackets, and bondable buccal tubes. The relatively low viscosity of the resin allows it to form a fillet at the edges of the bracket which reduces the need to remove excess adhesive, also known as flash.

Intended Use of The Device:
The intended use of APC™ Flash-Free Adhesive is as a light cure orthodontic adhesive that is designed to be used in bonding orthodontic appliances for orthodontic treatment.

Technological Characteristics:
APC™ Flash-Free is substantially equivalent in design features to the predicate devices. These features include an adhesive pre-applied to a bracket bonding base and then light-cured to adhere the appliance to the tooth.

Device Material:
APC™ Flash-Free Adhesive and the predicate devices Adhesive Precoated Brackets and APC™ Plus Adhesive are substantially equivalent in composition. All three devices contain methacrylate based resins and fillers. Additionally, all three devices are cured by exposure to visible light.

Device Design:
APC™ Flash-Free Adhesive and the predicate devices Adhesive Precoated Brackets and APC™ Plus Adhesive are substantially equivalent in design. All three devices consist of an orthodontic appliance which is delivered with a methacrylate-based adhesive precoated (pre-applied) to the bonding base and packaged in a heat sealed plastic blister. Further, all three devices are cured via exposure to visible light.

Nonclinical Performance Testing:
The nonclinical testing performance analysis shows that APC™ Flash-Free Adhesive performs comparably to the predicate devices as follows:

1. The bond strength test demonstrates that Adhesive Precoated Brackets, APC™ Plus Adhesive, and APC™ Flash-Free Adhesive perform comparably and provide the minimum bond strength to hold a bracket to a tooth.

2. The primer compatibility test demonstrates that APC™ Plus Adhesive and APC™ Flash-Free Adhesive perform comparably and provide the minimum bond strength to hold a bracket to a tooth when used with Transbond MIP Primer (3M™ Dent System, K962785), and Transbond Plus SEP Primer (Modification to Prompt™ L-Pop™, K001494).

3. Accelerated aging of bonds by thermocycling demonstrates that APC™ Plus Adhesive and APC™ Flash-Free Adhesive perform comparably and provide the minimum bond strength to hold a bracket to a tooth following a specified number of cycles between hot and cold environments.

4. The ambient light stability test demonstrates that APC™ Plus Adhesive and APC™ Flash-Free Adhesive perform comparably and provide the minimum bond strength to hold a bracket to a tooth following exposure to ambient light.

Clinical Performance Testing:
No clinical performance testing was conducted with APC™ Flash-Free Adhesive.

Substantial Equivalence:
Information provided in this 510(k) submission ahows that APC™ Flash-Free Adhesive is substantially equivalent to the predicate devices, Adhesive Precoated Brackets and APC™ Plus Adhesive, in terms of intended use, indications for use, composition, performance and technological characteristics. The conclusions drawn from the nonclinical performance (bench) testing and the biocompatibility assessment demonstrate that APC™ Flash-Free Adhesive is safe and effective for its intended use and performs as well as the predicate devices.

This 510(k) submission includes data from bench testing to evaluate the performance of APC™ Flash-Free Adhesive compared to the predicate devices. The properties evaluated include Compatibility with Orthodontic Primers, Accelerated Aging of Bonds by Thermocycling, and Ambient Light Stability.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Re: K113197
Trade/Device Names: APC™ Flash-Free Adhesive
Regulation Number: 21 CFR 872.3750
Regulation Name: Bracket Adhesive Resin and Tooth Conditioner
Regulatory Class: II
Product Codes: DYH, EJF, and NJM
Dated: January 25, 2012
Received: January 26, 2012

Dear Mr. Wang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K113197

Indications for Use

510(k) Number (if known):

Device Name: *APC™ Flash-Free Adhesive*

Indications for Use:

APC™ Flash-Free Adhesive is indicated for use in bonding orthodontic appliances for orthodontic treatment.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

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